

Food and Drug Administration

(dollars in millions)

	1996 Actual	1997 Enacted	1998 Request	Request +/- Enacted
Program Level	\$980	\$996	\$1,064	+\$68
Budget Authority	877	888	820	-68
Outlays	865	918	852	-66
FTE	9,172	9,180	9,180	0

Summary

The FY 1998 budget request for the Food and Drug Administration (FDA) is \$1,064 million in program level, a 7 percent increase over FY 1997, of which \$244 million is derived from targeted industry-specific user fees. In addition, FDA is proposing two new important public health initiatives--food safety and youth tobacco prevention.

The FDA is the principal consumer protection agency of the Federal government. FDA's goal is to protect the public health through the prevention of injury or illness due to unsafe or ineffective products. FDA's authority is to ensure that food is safe and wholesome; drugs, biological products, and medical devices are safe and effective, cosmetics are unadulterated; radiological products do not cause unnecessary exposure to radiation; and that all of these products are honestly and informatively labeled.

Food Safety

Late in 1996, an outbreak of E. coli-contaminated unpasteurized apple juice sickened dozens in several States and killed one child. To prevent future incidents such as this one caused by foodborne pathogens like E. coli and salmonella, FDA--in tandem with the Centers for Disease Control and Prevention, the U.S. Department of Agriculture and the Environmental Protection Agency--is launching an important food safety initiative. The FY 1998 FDA request includes an additional \$24 million for six strategic components:

- Inspections--increase inspections to implement the Hazard Analysis Critical Control Point (HACCP) for seafood;
- Surveillance--create the ability to rapidly detect foodborne illness outbreaks;
- Coordination--increase coordination at all

levels of government;

- Education--provide food safety education programs and materials;
- Risk assessment--improve health risk estimates to facilitate the development and evaluation of surveillance and risk reduction plans; and
- Bioscience Research--develop new improved tools and methods to identify and evaluate foodborne hazards.

Youth Tobacco Prevention

Every year, another 1 million young people become regular smokers, and one-third of them will eventually die prematurely as a result of their smoking. In August 1996, President Clinton announced to the American public FDA's final rule designed to decrease young people's use of tobacco by 50 percent over seven years through the regulation of nicotine-containing tobacco products. FDA's budget includes \$34 million to implement this important regulation. This will be done through outreach with retailers, state and local officials, communities, and the media. Developing a strong outreach program is one of the most effective ways to increase compliance with the new rule.

FDA will also emphasize efforts by commissioning State and local offices who will enforce the final rule by conducting compliance checks to make sure that retailers do not sell tobacco to minors. FDA will establish the necessary training experiences for those State and local officials conducting the compliance checks.

User Fees

The FY 1998 budget builds upon the successful implementation of the Prescription Drug User Fee Act (PDUFA) and the Mammography Quality Standards Act (MQSA) which authorized the collection of user fees for reviewing drug applications and inspecting mammography facilities, respectively. The FY 1998 budget proposes reauthorization of these two programs -- PDUFA (\$91 million) and MQSA (\$14 million). Under PDUFA in FY 1996, FDA approved 121 new drug applications (NDAs) with a median approval time of 15 months--70 percent more than in FY 1995. This was achieved while decreasing the median approval time by 20 percent. Of these NDAs, 42 were approved in 12 months or less--110 percent increase over FY 1995.

Consistent with recommendations of the Vice President's 1993 National Performance Review, the budget also includes \$131 million in user fees that will be dedicated to finance other areas of FDA regulation such as medical devices, animal drug approvals, import inspections, generic and over-the-counter drug applications, and establishment fees. In addition FDA will continue the collection of fees for export certification and insulin and color additive certifications.

Arkansas Regional Laboratory

FDA is requesting \$14.6 million in FY 1998 to complete construction of the Arkansas Regional Laboratory in Jefferson, Arkansas. The Arkansas Regional Laboratory is a cornerstone of FDA's consolidation plan that will provide State-of -the-art and laboratory programs.

FDA OVERVIEW

(dollars in millions)

	<u>1996</u> <u>Actual</u>	<u>1997</u> <u>Enacted</u>	<u>1998</u> <u>Request</u>	<u>Request</u> <u>+/- Enacted</u>
Salaries and Expenses				
Foods	\$201	\$200	\$220	+20
Drugs	407	413	424	+11
Medical Devices	157	160	166	+6
National Center for Toxicological Research	31	31	31	0
Tobacco	5	5	34	+29
Other Activities	94	90	90	0
Other Rent & Rent Related Activities	<u>22</u>	<u>23</u>	<u>23</u>	<u>0</u>
Subtotal, Salaries & Expenses	\$917	922	988	+66
 GSA Rental Payments	 46	 46	 46	 0
Buildings & Facilities	12	21	23	+2
Certification Fund	5	5	5	0
Export Certification	<u>0</u>	<u>2</u>	<u>2</u>	<u>0</u>
 Total, Program Level	 \$980	 \$996	 \$1,064	 +\$68
 Less User Fees:				
Current Law:				
Revolving Fund	5	5	5	0
Export Certification	0	2	2	0
Proposed Law:				
Prescription Drugs	85	88	91	+3
Mammography Inspections	13	13	14	+1
Food & Cosmetics	0	0	47	+47
Drugs	0	0	25	+25
Animal Drugs & Feeds	0	0	13	+13
Medical Devices	0	0	45	+45
Biologics	<u>0</u>	<u>0</u>	<u>2</u>	<u>+2</u>
Subtotal, User Fees	<u>\$103</u>	<u>\$108</u>	<u>\$244</u>	<u>+\$136</u>
 Total, Budget Authority	 \$877	 \$888	 \$820	 -\$68
 FTE	 9,172	 9,180	 9,180	 0